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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,561	09/19/2003	Richard A. Clark	001.00254	4600

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EXAMINER	
KIM, VICKIE Y	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,561	CLARK ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,9-12,16 and 17* is/are pending in the application.

4a) Of the above claim(s) *1 and 3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12, 16-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 10/17/06. Upon entering the amendment, the claims 1, 9, 12, 16 are amended and the claims 2, 4-8, 13-15 are canceled. New claim 17 is added.

2. The claims 1, 3, 9-12 and 16-17 are pending and the elected claims 9-12 and 16-17 are presented for the examination.

Response to Amendment

3. Applicant's amendments are entered properly. However, in view of amendment filed, the new ground(s) of rejection is prepared since scope changes is made into the claims currently amended.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Pines et al(US 5330974).

The claims are drawn to a composition comprising fibrinogen and lipids, wherein the fibrinogen has a purity of above about 90%.

Pines teaches a therapeutically effective fibrinogen composition used as an adhesive or sealant, see abstract. Pines' composition comprising a fibrinogen which has purity of about 90% or greater(see col.3, lines 36-39) and fatty acids(see col. 10, lines 9). Fatty acids is the lipid building blocks and lipids are composed of some sort of fatty acid arrangement(see evidentiary document about definition of lipids at PTO-892, "BIO 113") , and thus, one would have been readily envisaged that Pines et al' s composition includes fibrinogen(purity about 90% or greater) and lipids.

All the critical elements required by the instant claims are well taught and the scope of the instant invention is well encompassed by the cited reference and thus, the claimed subject matter is anticipated and not patentable over the prior art of the record.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 10-12 are 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pines et al(US'974) or MacOhee et al(US6117425), individually in view of Laub et al(US5834420).

Pines' teaching is mentioned in 102 rejection(see above). Pines also teaches that the fibrinogen is prepared by glycine precipitation(see col.3, lines 36-39).

MacPhaee teaches a composition comprising purified fibrinogen and lipids(see claim 1 and claim 35, especially col. 10, lines 1-25) .

Applicant's claims differ in that they require a specific purified fibrinogen, for instance, claim 10 require 95% and claim 11 require about 99% purified fibrinogen.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Pines et al's or MacPhee's teaching with Laub's teaching to make highly purified fibrinogen composition(95% or 99%) because Laub teaches that glycine precipitation yields a highly purified fibrinogen and furthermore, repeated glycine precipitation yields pure fibrinogen having greater than 98%+/- 2% purity (see Laub's patent, col.5, lines 1--65). Therefore, latter references remedy the deficiency of Pines et al. or MacPhee's teaching. Thus, one would have been motivated to make highly puridfied fibrinogen and lipids containing composition prepared by the glycine precipitation because the said preparation including repeated precipitation allows the fibrinogen to increase its clottability more than about >98%, preferably > 98% which in turn, would maximize fibroblast migration when it is contacted into wound site in vivo.

One would have been motivated to make such modification with reasonable expectation of success because the techniques and skills to purify fibrinogen more than 98% is well taught and there is advantages such as improved fibroblast migration and free from viral contamination, etc so that one would have been motivated to replace Pines's (greater than 90%) or MascPhee (Purified fibrinogen) with Laub(greater 98% +/- 2%).

Even though product-by-process claim(i.e. claim 17) is limited by and defined by the process, determination of patentability is based on the product itself. The

patentability of a product does not depend on its method of production. If the product in the product by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process, *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966(Fed. Cir. 1985). The structure implied by the process steps should be considered when assessing the patentability of product –by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would by expected to impart distinctive structural characteristics to the final product, See e.g., *In re Garnero*, 412 F. 2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). Thus, Claim 17 is included in this rejection .

One would have been motivated to make highly purified fibrinogen composition(95% or 99%) and the modification is well within the skilled level of artisan having ordinary skill in the art, and claims are obvious over the prior art of the records.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

4. No claim is allowed.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
Primary Patent Examiner
January 5, 2007
Art unit 1618